IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Abbott Diabetes Care, Inc., *a Delaware corporation*,	)	
Plaintiff,	)	C.A. No. 05-590 (GMS)
v.	)	
DexCom, Inc., *a Delaware corporation*,	)	
Defendant.	)	

DEXCOM, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE "AMENDED COMPLAINT" AND RENEWED MOTION TO DISMISS COMPLAINT

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I. NATURE AND STAGE OF PROCEEDINGS AND SUMMARY OF ARGUMENT

Without leave of court, Abbott's Diabetes Care, Inc. ("Abbott") filed what it called an "Amended Complaint" (D.I. 55), setting forth events that occurred more than seven months after its initial complaint. A pleading that sets forth "transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented" is a "supplemental pleading" under Federal Rule of Civil Procedure 15(d), not an "amended" pleading under Rule 15(a). Leave of court is required for a supplemental pleading. Because Abbott did not seek leave of court to file its supplemental pleading, it should be stricken.

The "Amended Complaint" should otherwise be dismissed because this Court lacked jurisdiction over Abbott's original complaint and, under controlling Federal Circuit authority, lacks jurisdiction over Abbott's "Amended Complaint." As set forth in detail in DexCom, Inc.'s ("DexCom's") Opening and Reply Briefs in Support of Its Motion to Dismiss (D.I. 6, 19, herein incorporated by reference), no case or controversy existed between the parties when Abbott filed its complaint on August 11, 2005. To the extent that DexCom was seeking FDA approval for a continuous glucose monitoring system ("the STS system"), that activity was protected as a matter of law under 35 U.S.C. § 271(e)'s safe harbor for activity related to FDA approval. DexCom did not have a product or FDA approval to market its STS system until over seven months after Abbott filed its complaint. While post-August 11, 2005 activity, including the launch of DexCom's product, may have triggered a case or controversy between the parties, one did not exist when Abbott filed its original complaint. Under these exact circumstances, the Federal Circuit has held that "later events may not create jurisdiction where none existed at the time of filing." *GAF Building Materials Corp. v. Elk Corp.*, 90 F.3d 479, 483 (Fed. Cir. 1996)

(citing *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 635 (Fed. Cir. 1991)). Thus, the filing of an amended complaint does not cure Abbott's premature forum-shopping from August 2005, and DexCom's motion to dismiss should still be granted.

To the extent the Court finds that there was an actual case or controversy, the Court should exercise its discretion not to hear the case. All four of the patents in the original complaint are undergoing reexamination. Hearing the case now would be a wasteful exercise in light of the statistical likelihood that the U.S. Patent and Trademark Office ("PTO") will find invalid or substantially alter the claims of Abbott's asserted patents.

II. STATEMENT OF FACTS

On August 11, 2005, Abbott filed a Complaint (D.I. 1, "the original complaint") against DexCom alleging patent infringement and seeking declaratory relief. Abbott claimed that DexCom's STS system, once approved by the FDA, would infringe four Abbott patents (collectively "the four original patents"). Those patents are now undergoing reexamination before the PTO pursuant to DexCom's request. The PTO determined that each reexamination request raised substantial questions about the validity of all independent claims in the four original patents in light of previously undisclosed prior art references. (*See generally* D.I. 46.)

DexCom filed a Motion to Dismiss the Complaint (D.I. 5) as premature because:

(1) DexCom's STS system had not been approved by the FDA, may never have been approved, and may have changed prior to approval; and

(2) with regard to Abbott's allegations regarding DexCom's display of the STS system at two scientific conferences, such use was exempt from infringement under 35 U.S.C.

§ 271(e)(1) and binding Federal Circuit precedent for activity related to the development and submission of information to the FDA.

After continued dialogue between DexCom and the FDA, DexCom ultimately received FDA approval and sold its first non-experimental STS system around March 27, 2006 – more than seven months after being sued by Abbott for patent infringement. To the extent the Court disagrees that it lacks jurisdiction and chooses to exercise it in this case, DexCom has separately sought a stay pending reexamination of the four original patents. (D.I. 25, 26, 39.)

On June 29, 2006, the Court assisted the parties with a discovery dispute involving the number of claims asserted by Abbott. Specifically, DexCom sought the Court's assistance because Abbott was asserting 110 claims from the four original patents and would not narrow its list of asserted claims to a manageable number.

Through the "Amended Complaint" at issue in this motion, Abbott accused DexCom of infringing three additional patents – Nos. 6,990,366; 5,899,855; and 6,134,461 ("the three new patents"). The three new patents were added to this case just five days before the parties were to begin the claim construction process with the exchange of disputed claim terms. DexCom will separately seek the Court's assistance with the scheduling issues arising from the introduction of the three new patents so close to the claim construction deadlines.

III. ARGUMENT

A. The "Amended Complaint" Should Be Stricken for Failure to Seek Leave of Court.

Abbott sought to end-run the Court's authority by calling its June 27, 2006 pleading an "Amended Complaint" (which does not always require leave of court), when in reality it is actually a "supplemental pleading" (which *always* requires leave of court). A

supplemental pleading is one that "set[s] forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." Fed. R. Civ. P. 15(d); *see generally Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1188 (3d Cir. 1979) (distinguishing supplemental pleadings from amendments). Abbott's "Amended Complaint" sets forth events which have happened since the original complaint was prematurely filed on August 11, 2005. For example, the "Amended Complaint" references DexCom's March 2006 FDA approval and the subsequent launch of DexCom's STS system:

> 15. On March 27, 2006, DexCom received FDA approval to market its STS™ Continuous Glucose Monitoring System. DexCom has made, used, offered for sale and sold its STS device in the United States continuously since that date.
>
> 16. DexCom has been aware of the Abbott patents for a long time and, despite that fact, has continued to develop its product, has continued to promote its product, and has commercially launched its product.

(D.I. 55 ¶¶ 15-16; *see also* ¶¶ 13, 19-20, 24-25, 29-30, 34-35, 39-40, 44-45, 49-50.)

Federal Rule of Civil Procedure 15 draws a clear distinction between amended complaints and supplemental pleadings. Under Rule 15(a), a party may file an amended complaint "only by leave of court or by written consent of the adverse party," subject to two exceptions. One of these exceptions allows a plaintiff to file an amended complaint "at any time before a responsive pleading is served." Fed. R. Civ. P. 15(a). If Abbott's "Amended Complaint" were governed by Rule 15(a), that exception would apply here because DexCom has

not filed a responsive pleading while its motion to dismiss has been pending. But Abbott's filing is governed by Rule 15(d), which makes no exception from the requirement that Abbott first obtain leave of court. *See, e.g.*, *Bronson v. Horn*, No. 02-663, 2006 U.S. Dist. LEXIS 38791 at *4 (W.D. Pa. June 12, 2006) (attached as Exhibit A) ("Fed. R. Civ. P. 15(d) makes clear that a supplemental complaint may not be filed without leave of court."). Since Abbott's "Amended Complaint" discusses the March 2006 FDA approval, DexCom's product launch, and other "events which have happened since the date of the pleading sought to be supplemented," the "Amended Complaint" falls under Rule 15(d), not Rule 15(a). Abbott did not seek leave of court. Thus, the "Amended Complaint" should be stricken.

While leave of court for amendments made under Rule 15(a) "shall be freely given when justice so requires," Fed. R. Civ. P. 15(a), the same is not true for supplemental pleadings under Rule 15(d). *See, e.g.*, *Burns v. Exxon Corp.*, 158 F.3d 336, 343 (5th Cir. 1998) (affirming denial of leave to file supplemental pleading and noting that "[w]hile the text of Rule 15(a) provides that leave should be freely granted, the text of Rule 15(d) does not similarly provide."). Rule 15(d) instead provides that a court should grant leave to amend only "upon reasonable notice and upon such terms as are just." Even if this Court holds that Rule 15(a)'s liberal amendment standards are applicable to Abbott's Rule 15(d) supplemental pleading, the Court should strike the "Amended Complaint" for two reasons. First, Abbott has not sought leave of court. Second, leave of court should be denied where there is "undue delay, bad faith [,] or dilatory motive on the part of the movant . . . [or] undue prejudice to the opposing party by virtue of allowance of the amendment. . . ." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Lewis v. Foster*, No. 04-1350 GMS, 2006 U.S. Dist. LEXIS 45819 at *30 (D. Del. July 5, 2006) (attached as Exhibit B) ("The court has discretion to deny leave to amend when there exists

undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile."). Here, Abbott's "Amended Complaint" and its failure to seek leave of court are unduly prejudicial to DexCom and otherwise exhibit "undue delay" that is suggestive of dilatory motive.

Abbott's "Amended Complaint" injects three new patents into this case just days before the parties were to begin the claim construction process with their initial exchange of disputed claim terms. To the extent the Court's scheduling order (D.I. 31, modified by D.I. 58) applies to the "Amended Complaint," Abbott's "Amended Complaint" was not filed with the "reasonable notice" required under Rule 15(d). Abbott holds more than twenty patents in this field and most likely knew for months which ones it would add to this case. However, it did not reveal the identity of the three new patents until it filed its "Amended Complaint." While the Court's scheduling order permits the parties to add additional patents to the case by July 14, that does not allow Abbott to withhold the three new patents until the last minute and still satisfy Rule 15(d)'s "reasonable notice" requirement.

At the February 23 scheduling conference, Abbott stated that it was "right now" considering the addition of a single patent to the case. Abbott said nothing when the Court and DexCom discussed a proposed case schedule premised on the assumption that the additional patent would be from the same patent family as the four original patents. (D.I. 27 at 16:21-17:6; 31:5-10.) Abbott then waited more than four months, filed its "Amended Complaint" with no warning to DexCom, and added three patents, two of which are not from the same family (i.e., share the same specification) as the four original patents.

DexCom has been prejudiced by Abbott's unreasonable delay in introducing three new patents and eighty-six new claims just days before the parties were required to exchange disputed claim terms and otherwise begin the claim construction process. DexCom received no notice that Abbott intended to add these specific patents. The introduction of three new patents involving new subject matter requires that DexCom spend time studying the file histories, conducting further prior art searches, and retaining new consulting experts. This amounts to undue prejudice to DexCom requiring that leave to supplement (if it were sought) be denied.

By failing to seek leave of court, Abbott circumvented the Court's authority to decide whether leave should be granted in light of both DexCom's pending motion to dismiss and motion to stay the case pending the PTO's reexamination of the four original patents. As set forth in more detail below, Abbott prematurely filed its lawsuit well before DexCom made, used, sold, or offered to sell an accused product outside the context of seeking FDA approval under 35 U.S.C. § 271(e)(1). Under controlling Federal Circuit precedent, that DexCom has now entered the market with its product does not allow the Court to overlook the prematurity of the lawsuit when filed in August 2005. Similarly, by failing to seek leave of court, Abbott has effectively removed the Court's discretion to decide whether such a pleading should be allowed in light of DexCom's motion to stay pending reexamination of the four original patents.

Abbott's tactics amount to the "undue delay" suggestive of "dilatory motive" that courts consider when denying leave to file supplemental pleadings. Thus, even if the Court looks beyond Abbott's failure to seek leave of court, the Court should strike the "Amended Complaint."

B. The "Amended Complaint" Should Be Dismissed Because the Court Lacked Jurisdiction to Consider the Original Complaint.

Because the Court lacked jurisdiction over the original declaratory judgment complaint, this Court likewise lacks jurisdiction over the "Amended Complaint." *See, e.g.*, *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634-35 (Fed. Cir. 1991) (discussing "the well-established rule that a party seeking a declaratory judgment must plead facts *initially* sufficient to establish the existence of an actual controversy"); *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734 n.2 (Fed. Cir. 1988) ("The presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed."). DexCom's motion to dismiss the original complaint fully addressed why this Court lacked jurisdiction on August 11, 2005. (*See* D.I. 6, 19.) DexCom incorporates by reference its briefing on the motion to dismiss and does not repeat that briefing in detail here. For the reasons stated therein, the "Amended Complaint" should be dismissed.

1. The Court Lacked Jurisdiction to Hear the Original Complaint.

In determining whether a patentee's complaint under 28 U.S.C. § 2201 satisfies the Article III case-or-controversy requirement, the Federal Circuit requires that a defendant engage in "present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1373 (Fed. Cir. 2004) (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)). That determination is made from facts as they existed at the time Abbott filed its Complaint – August 11, 2005. *Lang v. Pacific Marine & Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed. Cir. 1990). Because there was no "accused device" to compare against the claims of

the four original patents – and because it was unclear whether or when such a device would exist – Abbott's request for a declaration of infringement was premature and should be dismissed.

Because there was no actual controversy between the parties at the time of the original complaint, the Court has no discretion to hear the declaratory judgment count of Abbott's complaint. *See Spectronics*, 940 F.2d at 633-34 ("When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."). In Count I of its original complaint, Abbott sought a "judicial declaration that DexCom's product *will infringe* one or more claims of each of Abbott's patents." (D.I. 1 ¶ 25 (emphasis added).) The issue of *future* infringement, however, was not ripe for adjudication. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992). In *Telectronics*, the patentee (Telectronics) filed a complaint against Ventritex before Ventritex's implantable defibrillator had received FDA approval. Ventritex moved to dismiss on the grounds that the declaratory judgment claim sought an advisory opinion. The district court granted defendant's motion, and the Federal Circuit affirmed, stating that the district court "could have correctly ruled that the case lacked sufficient immediacy and reality to meet the actual controversy requirement" because defendant's device was undergoing FDA review and "was years away from potential FDA approval." *Id.* The Federal Circuit also emphasized that "[t]here was no certainty that the device when approved would be the same device that began clinical trials." *Id.*

DexCom's pending motion to dismiss cites and discusses other cases in which complaints were dismissed because the accused infringer did not have an FDA-approved product to compare to the patent claims. (D.I. 6 at 10-13; D.I. 19 at 2-9.) One additional case that issued since the original briefing is Judge Farnan's decision in *Benitec Austl. Ltd. v. Nucleonics, Inc.*,

No. 04-0174 JJF, 2005 U.S. Dist. LEXIS 22008 (D. Del. Sept. 29, 2005) (attached as Exhibit C). In that case, one issue before the Court was whether there was a case or controversy between the parties concerning the defendant's use of allegedly patented RNAi technology. Judge Farnan dismissed the case for lack of case or controversy because the product at issue did not yet have FDA approval and there was "no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed." *Id.* at *9. To the extent the defendant was using the RNAi technology, such use was necessarily exempt under 35 U.S.C. § 271(e)(1)'s safe harbor, and, therefore, not sufficient to trigger the case or controversy requirement. *Id.* at *7-*9. The same was true for DexCom at the time Abbott filed suit – DexCom was not in position to get FDA approval the year that Abbott filed suit, and even if it were likely that some form of the DexCom device was on track for eventual approval, there was no certainty that it would be the same device DexCom was testing at the time of Abbott's complaint.

2. DexCom's FDA Approval and Product Launch Seven Months After the Original Complaint are Irrelevant Because Abbott Was Required to Demonstrate Jurisdiction the Day the Original Complaint was Filed.

If the Court lacked jurisdiction on August 11, 2005, the Court lacks jurisdiction today, and Abbott's "Amended Complaint" cannot cure the jurisdictional defects as a matter of law. The Federal Circuit addressed whether an amended complaint can cure jurisdictional defects and squarely held that subsequent events cannot create jurisdiction where none existed at the time of filing. *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 483 (Fed. Cir. 1996).

In *GAF*, Elk had received a Notice of Allowance, paid the issue fee for its pending patent application, and thereafter notified its competitor, GAF, that GAF's product

would infringe once the patent issued. GAF responded with a declaratory judgment action of noninfringement and invalidity before the PTO issued the Elk patent. *Id.* at 480. Elk's patent issued five weeks later, and without seeking leave of court, GAF amended its complaint to incorporate the patent's issuance. The district court ultimately dismissed the action because without an issued patent at the time of the original complaint, there was no case or controversy and the amended complaint could not cure that jurisdictional defect. *Id.* at 480-81. The Federal Circuit affirmed, agreeing that there was no case or controversy until the patent actually issued and further agreeing that the amendment to the complaint could not cure the original jurisdictional defect. *Id.* at 483 ("Later events may not create jurisdiction where none existed at the time of filing. . . . Rather, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed.") (quotation omitted). The Federal Circuit further noted that the amendment to the complaint was defective in any event because it amounted to a supplemental pleading and that GAF never sought leave of court as required by Rule 15(d). *Id.*

The facts of this case compel the same result as *GAF*. In *GAF*, there was no case or controversy for patent infringement because the PTO had not yet issued the Elk patent. Here, there was no case or controversy in August 2005 because the FDA had not yet approved DexCom's product design. Abbott speculated in its opposition that DexCom's FDA approval was a "foregone conclusion." (D.I. 17 at 14.) In DexCom's case "foregone conclusion" is quite an exaggeration, but issuance of the GAF patent was a "foregone conclusion," because the PTO had already issued a Notice of Allowance and the patentee had already paid the issue fee. *See* 35 U.S.C. § 151 ("Upon payment of [the issue fee], the patent shall issue."). Nevertheless, the Federal Circuit affirmed dismissal. Here, FDA approval was anything but a "foregone

conclusion" as evidenced by the seven months of continued "back and forth" with the FDA before DexCom received approval to market its STS system.

Like the patentee's amended complaint in *GAF*, Abbott's "Amended Complaint" is meaningless because (1) it cannot overcome the fact that there was no case or controversy at the time of the original filing, and (2) it failed to seek leave of court to file a supplemental pleading under Rule 15(d). Applying the Federal Circuit's rationale from *GAF*, this Court must dismiss Count I of the original complaint and each count of the "Amended Complaint."

C. Count II of the Original Complaint Failed To State A Claim For Which Relief Can Be Granted Because DexCom's Display At Two Scientific Conferences Was Exempt Under 35 U.S.C. § 271(e)(1).

Abbott's original complaint went beyond declaratory relief and also claimed that DexCom's actual conduct, as of the August 11, 2005 date of the original complaint, infringed the four original patents. Specifically, Abbott alleged that DexCom attended two diabetes-related "trade shows where it has publicized and displayed its product." (D.I. 1 ¶ 16.) As stated in detail in DexCom's motion to dismiss the original complaint (*see* D.I. 6 at 14-17; D.I. 19 at 9-13), "publicizing" and "displaying" a product are not acts of infringement as a matter of law. Moreover, DexCom's activity while awaiting FDA approval was protected under 35 U.S.C. § 271(e)(1). In its opposition, Abbott failed to identify a single non-ANDA case in which a court exercised jurisdiction over a patent dispute while the accused infringer awaited FDA approval.

The Federal Circuit addressed the issue of pre-approval display of a product at scientific conferences in *Telectronics* and held that attendance at such events was exempt under 35 U.S.C. § 271(e)(1). 982 F.2d at 1523. *Telectronics* is on "all fours" with the facts of this case, and its outcome controls here. In that case, defendant Ventritex was conducting clinical

trials on its implantable defibrillator as part of the FDA review process. During the clinical trials, Ventritex displayed and demonstrated its defibrillator at seven medical conferences, including conferences where non-physicians were present. In communicating with investors and the media, Ventritex's CEO provided updates on the status of the clinical trials, stating that early clinical results were promising. Telectronics filed a complaint seeking declaratory relief, alleging that Ventritex's actions at the seven scientific conferences were not exempt under § 271(e)(1). The only *conduct* (i.e., making, using or selling) that Telectronics alleged was "unrelated to FDA approval," and therefore outside of the protections of § 271(e)(1), was "Ventritex's demonstration of its defibrillator to some non-physicians at medical conferences." *Id.* On defendant Ventritex's motion to dismiss, the district court found that the alleged infringing conduct (i.e., demonstrations to non-physicians at trade shows) was exempt under 35 U.S.C. § 271(e)(1).[1] The Federal Circuit affirmed, holding that "such demonstrations constitute an exempt use reasonably related to FDA approval." *Id.* at 1523.

DexCom's alleged actions at scientific conferences were likewise exempt under § 271(e)(1). Although DexCom (like Ventritex) submitted data from its initial clinical trials, the FDA could have required DexCom to submit additional data to demonstrate the safety and/or effectiveness of its STS system. (*See* D.I. 6 at 15 and DexCom SEC filings cited therein; D.I. 7, Ex. C at 17 ("the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, *or may require us to pursue additional pre-clinical studies or clinical trials*.") (emphasis added).) The FDA permits "sponsors of clinical investigations to continue to enroll subjects [in clinical trials] at a pre-determined rate while a marketing application is being .

[1] The district court treated Ventritex's motion under Fed. R. Civ. P. 56.

. . reviewed by the Office." FDA Memorandum #D96-1, entitled "Continued Access to Investigational Devices During PMA Preparation and Review," dated July 15, 1996 (D.I. 7, Ex. H at 2). The FDA recognizes that "[s]uch a policy is scientifically sound as it allows the sponsors to collect additional safety and effectiveness data in support of the marketing application or to address new questions regarding the investigational device during this intervening period." *Id.* Because DexCom's facts so closely match those in *Telectronics*, adopting its reasoning and dismissing Count II is appropriate.

1. The Court Need Not Credit Abbott's "Trade Show" Allegations Regarding 35 U.S.C. § 271(e)(1) Because They Amount to Bald Assertions and Legal Conclusions.

Even if the Court does not find that DexCom's "trade show" activity was exempt under § 271(e)(1) as a matter of law, the Court can still dismiss the complaint for failure to state a claim under Rule 12(b)(6) because Abbott's conclusory allegations need not be credited. First, it is important to note that Abbott did not accuse DexCom of having "used" its invention at the so-called trade shows; nor did Abbott accuse DexCom of having "sold" or "offered to sell" an infringing product at those two shows. Abbott did not and could not base its infringement claim on its assertion that DexCom "displayed" its prototype at conferences, because "displaying" is not an infringing activity under 35 U.S.C. § 271(a). Instead, Abbott alleged that "DexCom's manufacture" of those products constituted an infringing act (D.I. 1 ¶¶ 17, 28), and that DexCom's "manufacture," which would otherwise be exempt under § 271(e)(1), is not exempt because the product was made – according to Abbott's allegation pled on "information and belief" – "for the purpose of showcasing it at trade shows." *Id.* The Court "need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Morse*

v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). Here, Abbott's allegations are just that – bald assertions and legal conclusions that need not be credited under Third Circuit law.

In the original complaint, Abbott expressly framed its § 271(e)(1) contention as a legal conclusion: "DexCom's manufacture of its product for the purpose of showcasing it at trade shows constitutes an infringing act, not exempted by 35 U.S.C. § 271(e)(1) relating to the collection of information for submission to the FDA." (D.I. 1 ¶ 28.) By pleading that DexCom's activity was "not exempted by 35 U.S.C. § 271(e)(1)," Abbott is just asserting a legal conclusion that the Court need not accept as true for purposes of a motion to dismiss. *Morse*, 132 F.3d at 906; *In Re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1430 (3d Cir. 1997) (affirming dismissal of complaint and noting that "[i]n asserting that there was 'no reasonable basis' for the November 1, 1993, earnings projection, plaintiffs simply mouth the required conclusion of law.").

In the "Amended Complaint," Abbott dropped the express reference to 35 U.S.C. § 271(e)(1) but repeated the same bald assertions found in the original complaint: "Upon information and belief, the products DexCom displayed at the trade shows were manufactured for the purpose of showcasing at the trade shows rather than for the purpose of gathering information for submission to the FDA." (D.I. 55 ¶ 17.) This still amounts to a "bald assertion" that need not be credited at the motion to dismiss stage. *See, e.g., Southern Volkswagen, Inc. v. Centrix Fin., LLC*, 357 F. Supp. 2d 837, 852 n.6 (D. Md. 2005) (dismissing count and noting that Plaintiff's "bald assertion that Defendant made the defamatory statement with 'the intent to cause economic harm and injury to [Plaintiff's] business' is not sufficient to withstand scrutiny under 12(b)(6)"). Recasting its § 271(e)(1) exemption argument as a factual conclusion does not require that this Court accept it as true. *See generally* 2 *Moore's Federal Practice* § 12.34[1][b]

(3d ed. 2006) (noting that "[c]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss") (citations omitted).

2. Even if the Court Credits the Trade Show Allegations and Finds That "Case and Controversy" Jurisdiction is Present, the Court Should Decline to Exercise Jurisdiction.

Finally, even if jurisdiction does exist (and it does not), the Court should decline to exercise jurisdiction for important policy reasons. *See Minnesota Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991) (even if plaintiff alleges facts sufficient such that justiciable controversy exists, court has discretion to decline the declaratory judgment jurisdiction). DexCom outlined these arguments in its earlier briefing. (D.I. 19 at 13-15.) In addition, the PTO ordered reexamination of the four original patents since the briefing on the original motion to dismiss. Continued litigation in the face of a pending reexamination proceeding is fraught with the potential for the waste of judicial resources given that, "[g]enerally speaking, the PTO invalidates 10% of the patents it reexamines and amends the claims in 64%." *Tap Pharm. Prods., Inc. v. Atrix Labs., Inc.*, 70 U.S.P.Q. 2d 1319, 1320 (N.D. Ill. 2004). The court should "not expend unnecessary judicial resources by attempting to resolve claims which may be amended, eliminated, or lucidly narrowed by the patent reexamination process and the expertise of its officers." *Hewlett-Packard Co. v. Acuson Corp.*, No. C-93-0808 MHP, 1993 U.S. Dist LEXIS 6449 at *4 (N.D. Cal. May 6, 1993) (attached as Exhibit D); *see also Alloc, Inc. v. Unilin Decor N.V.*, No. 03-253 GMS, 2003 U.S. Dist. LEXIS 11917 (D. Del. July 11, 2003) (attached as Exhibit E) (granting stay pending reexamination); *Pegasus Dev. Corp. v. Directv, Inc.*, No. 00-1020 GMS, 2003 U.S. Dist. LEXIS 8052 (D. Del. May 14, 2003) (attached as Exhibit F) (same).

IV. CONCLUSION

With its original complaint, Abbott engaged in premature forum shopping. The Court had no jurisdiction over that complaint and therefore lacks jurisdiction over the "Amended Complaint." Accordingly, both should be dismissed.

By not seeking the Court's permission to file its "Amended Complaint," Abbott circumvented this Court's authority. For that reason alone, it should be stricken. Even if the Court overlooks the failure to seek leave of court and also finds a case or controversy between the parties as of August 11, 2005, leave to file the supplemental pleading should be denied because the introduction of three new patents ten months into this case is unduly prejudicial to DexCom, and the prejudice was caused by Abbott's tactical delay.

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DATED: July 12, 2006

CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on July 12, 2006, I caused to be electronically filed a true and correct copy of the foregoing document, DexCom, Inc.'s Opening Brief in Support of Its Motion To Strike "Amended Complaint" and Renewed Motion to Dismiss Complaint, with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on July 12, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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